

### **Remarks**

Claims 1-9 and 38-56 are pending. No amendments have been presented and as such, no new matter enters by way of the present response.

#### **1. *Withdrawn Objections and Rejections***

Applicants acknowledge and thank the Examiner for indicating that the objections to claims 38-43, as well as the rejections under 35 U.S.C. §§ 101, 112, second paragraph, and 102 have been withdrawn.

#### **2. *Double Patenting***

Claims 1-4 and 6-9 stand rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 8-16 of U.S. Patent No. 6,689,941. *Final Action* at page 3.

The Examiner has provided no support for the assertion that U.S. Patent No. 6,689,941 may be used as the basis of an obviousness-type double patent rejection. The statute provides that “a patent issuing on an application with respect to which a requirement for restriction under [35 U.S.C. § 121] has been made, ... shall not be used as a reference ... against a divisional application ..., if the divisional application is filed before the issuance of the patent on the other application.” 35 U.S.C. § 121. The instant application was filed on September 16, 2003 as a divisional application of U.S. Serial No. 09/822,817 (the “’817 Application,” now U.S. Patent No. 6,689,941, issued February 10, 2004). The ‘817 Application was the subject of a restriction

requirement under 35 U.S.C. § 121 mailed by the Office on January 8, 2002. *See*, Office Action mailed January 8, 2002 in U.S. Serial No. 09/822,817<sup>1</sup>.

Accordingly, Applicants request reconsideration and withdrawal of the obviousness-type double patenting rejection of claims 1-4 and 6-9 in light of the restriction requirement issued in the '817 Application. The Examiner is specifically requested to clarify the Patent Office's position if the above response does not in the Examiner's opinion overcome the double patenting rejection.

**3. *Rejections under 35 U.S.C. § 112, first paragraph, Written Description***

Claims 1-3, 5-7 and 41-56 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly containing "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *Final Action* at page 3. The Examiner states that the "rejection is repeated for the reasons of record as set forth in the Office Action mailed August 25, 2005." *Id.* Applicants respectfully disagree.

Although the Examiner acknowledges that "the specification discloses numerous physiological characteristics of the iceberg lettuce cultivars," the Examiner asserts that this is not sufficient because "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." *Final Action* at pages 3-4.

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<sup>1</sup> Applicant respectfully draws the Examiner's attention to a second, different restriction requirement mailed in the present application in the Office Action mailed May 9, 2005.

Applicants respectfully disagree with the Examiner's contention that despite the characteristics of the iceberg lettuce cultivars described in the present specification, "there is no evidence in the specification that would allow one skilled in the art to conclude that Applicant has possession of all lettuce plants having the claimed characteristics." *Id.* at page 4. The test, promulgated by the Federal Circuit, stipulates that a generic claim may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus, written description is satisfied. *See, Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). In the present case, Applicants have satisfied that test for written description by providing a structural feature, namely characteristics that distinguish members of the claimed genera from non-members, such as an iceberg lettuce cultivar having a first outer leaf having a length to width ratio between about 1.2 to about 2.7.

Applicant maintain that the specification and claims as originally filed adequately support the claimed invention. For example, as the Examiner acknowledges, the specification discloses numerous physiological characteristics of the iceberg lettuce cultivars, for example, an iceberg lettuce cultivar having a first outer leaf having a length to width ratio between about 1.2 to about 2.7. *See, e.g.*, specification at page 9, paragraph [00044]. In addition, the specification describes additional aspects of the iceberg lettuce cultivars, such as spatulate leaf shapes, elliptical leaf statures, leaf colors, and head formations. *See*, specification at page 9, paragraph [00042] through page 10, paragraph [00046] Moreover, the specification exemplifies multiple *L. sativa* cultivars having a first outer leaf having a length to width ratio between about 1.2 and about 2.7. *See, e.g.*, specification at page 17, Table 3, page 15, Table 2, page 19, Table 4, page 21, Table 5,

and page 13, Table 1. The specification further discloses and exemplifies other embodiments of the iceberg lettuce cultivars, such as resistance to corky root rot and lettuce mosaic virus. Specification at page 7, paragraph [0032], page 22, paragraph [00065], through page 25, paragraph [00080]. Thus, there is no deficiency in the written description support for the iceberg lettuce cultivars. Therefore, claims 1-7 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

The Examiner also argues that claims 41-45 are not described apparently because the “specification does not describe the other lettuce plant or plants that are to be crossed with PSR 6425 nor is there a description of their genetic, morphological, and/or other physiological background.” *Office Action*, mailed August 25, 2005 at page 6. As set forth above, the specification describes multiple lettuce lines having a first outer leaf having a length to width ratio between about 1.2 and about 2.7, including, lettuce line PSR 6425, and provides numerous characteristics of the line, such as leaf length to width ratios between about 1.2 to about 2.7, as well as disease resistance, and other characteristics. Based on Applicants disclosure and knowledge of the art, the person of ordinary skill in the art would be aware of the numerous lettuce varieties that can be used in breeding programs with an iceberg lettuce cultivar of PSR 6425. *See, Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005). Again, there is no deficiency in the written description support for the claimed invention. Therefore, claims 41-45 also satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

For these reasons, claims 1-3, 5-7 and 41-56 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. As such, Applicants respectfully request reconsideration and

withdrawal of the rejection under 35 U.S.C. § 112, first paragraph for the alleged lack of written description.

**4. *Rejections under 35 U.S.C. § 112, first paragraph, Enablement***

Claims 1-3, 5-9 and 38-56 also stand rejected under 35 USC § 112, first paragraph, as allegedly not being enabled by the specification commensurate with the scope of the claims. *Final Action* at page 5. The Examiner states that the “rejection is repeated for the reasons of record as set forth in the Office Action mailed August 25, 2005.” *Id.* This rejection is respectfully traversed for at least the reasons which follow.

The Examiner argues that “the deposit information is incomplete as there is no reference regarding the criteria set forth in 37 C.F.R. 1.801-1.809 or any statement by an attorney of record over his or her signature.” *Id.* at page 6.

Applicants reiterate that a Deposit Declaration will be provided with an attached copy of the Receipt of an Original Deposit, indicating that lettuce cultivar PSR 6425 has been deposited upon an indication that the subject matter is otherwise allowable. In light of the filing of this Applicants request that this rejection under 35 U.S.C. § 112, be held in abeyance.

In addition, the Examiner alleges that the claims are not enabled by the specification commensurate with the scope of the claims. *Final Action* at pages 6-8.

The Final Action asserts that “[o]ne of skill in the art would not know the starting material to produce the claimed invention with the exact characteristics as claimed; therefore, one skilled in the art would have to screen literally thousands of lettuce plants to find which, if

any, would have the exact characteristics of the claimed invention.” *Id.* Applicants respectfully disagree and submit that the specification is enabling for an iceberg lettuce cultivar as claimed.

As previously set forth, the specification discloses sufficient guidance to produce the claimed lettuce cultivars. For example, the specification describes methods for breeding iceberg lettuce cultivars of the present invention, such as pedigree selection methods and discloses selection criteria that can be employed in such methods. *See*, specification at page 6, paragraph [00026] through page 7, paragraph [00031]. Moreover, the specification describes numerous characteristics of the iceberg lettuce cultivars of the present invention, for example, leaf shape and color, leaf length to width ratio, and disease resistance. *See*, Specification at page 9, paragraph [00042] through page 10, paragraph [00046]. In addition, the specification provides working examples of the preparation of iceberg lettuce cultivar PSR 6425, as well as other iceberg lettuce cultivars within the genus of claimed iceberg lettuce cultivars. *See, e.g.*, Specification at page 10, paragraph [00048] through page 22, paragraph [00064]. As such, the specification provides ample guidance to the skilled artisan to produce the lettuce plants as presently claimed.

The Examiner argues however, that the “specification does not provide any guidance with regards to the other lettuce plant or plants that are to be crossed with PSR 6425 nor is there any guidance regarding their genetic, morphological, and/or physiological background.” *Office Action* mailed August 25, 2005 at page 11. As set forth above, Applicant has described the claimed iceberg lettuce cultivars. The skilled artisan, based on the specification, would be able to obtain F<sub>1</sub> hybrids using such cultivars without undue experimentation. It is well established

that Applicants need not teach conventional and well-known techniques (*see, e.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000)), which would include lettuce breeding techniques for obtaining F<sub>1</sub> hybrids of the iceberg lettuce cultivars, as well as parameters for selecting parents for use in such techniques. Further, the performance of routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976). Time and difficulty of experiments are not determinative if they are merely routine. M.P.E.P. § 2164.06, page 2100-192. That is, experimentation is not necessarily undue simply because it is complex, if the art typically engages in such experimentation. *See In re Certain Limited-Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174, (Int'l Trade Comm'n 1983) *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 U.S.P.Q. 428 (Fed. Cir. 1985).

The Examiner maintains his reliance on Kevern (U.S. Patent No. 5,850,009), Carlone (U.S. Patent No. 5,763,755), Segebart (U.S. Patent No. 5,304,719), and Segebart (U.S. Patent No. 5,367,109) to support the proposition that there is some level of unpredictability in plant breeding involving “factors beyond the breeder’s control” *Final Action* at page 7. While the references cited by the Examiner discuss difficulties in progeny selection in corn breeding programs, the Examiner has still provided no nexus between the cited references relating to corn breeding with iceberg lettuce breeding programs. Accordingly, the Examiner’s reliance on the cited references is misplaced.

To the extent that the Office suggests there is a requirement for *a priori* predictability without recourse to any experimentation, that position is without legal support. *Cf. Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984) (“[t]hat some experimentation is necessary does not preclude enablement”). The proper test of enablement in such a situation is whether the disclosure “adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility.” *See In re Vaeck*, 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991).

The Examiner also refers to language in the instant specification to support the argument that “[t]he specification teaches that methods of producing iceberg lettuce plants having various characteristics are unpredictable.” *Office Action* at page 13. However, the Examiner reads the passages out of context and appears to ignore that the cited passages indicate the problems associated with lettuce breeding that the teachings of the present invention overcome. As such, the Examiner’s reliance on the statements in the specification are misplaced as well.

Moreover, the Examiner relies on Ryder, *et al.* to support the proposition that “epistatic interactions can occur in lettuce cultivars.” *Final Action* at page 8. However, the Examiner does not correlate this alleged epistatic interactions discussed in Ryder to any epistatic interactions between the characteristics of the claimed iceberg lettuce cultivars. Moreover, the Examiner appears to require the Applicants to show that “epistatic interactions do not occur in lettuce breeding.” *Final Action* at page 8. As discussed above, the specification provides ample guidance for the production of the claimed hybrid lettuce plants, parts thereof, and seeds. Even

if epistatic interactions occur in lettuce, the skilled artisan would still be able to practice the claimed invention based on the disclosure of the present application as discussed above.

Accordingly, for at least these reasons, the enablement rejection of claims 1-3, 5-9 and 38-56 under 35 USC § 112, first paragraph, is traversed, and reconsideration and withdrawal of this rejection is respectfully requested.

**5. *Rejections under 35 U.S.C. §§ 102/ 103***

Dependent claims 41-45 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Bassett (J. Amer. Soc. Hort. Sci. 100(2): 104-105, 1975). *Office Action* at page 16.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations.

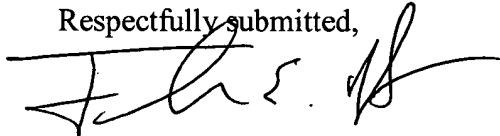
The cited reference does not teach or suggest all of the claim limitations of dependent claims 41-45. As the Examiner apparently acknowledges, Bassett *et al.* does not disclose, or suggest, an *L. sativa* L. line PSR 6425, PSR 6595, or PSR 6032, as recited in independent claim 38. The Federal Circuit has noted that "[d]ependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious." *See, In re Fine*, 837 F.2d 1071, 1076, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). As such, what ever else Bassett *et al* discusses, it does not disclose or suggest an F<sub>1</sub> hybrid *Lactuca sativa* or iceberg lettuce plants having as one or more parents a *Lactuca sativa* L. plant grown from the seed of *L. sativa* L. line PSR 6425, PSR 6595, or PSR 6032.

Accordingly, for at least the foregoing reasons, the rejection of claims 41-45 under 35 U.S.C. §§ 102 and 103 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

### CONCLUSION

In view of the foregoing arguments and amendments, each of the presently pending claims is believed to be in immediate condition for allowance. All of the stated grounds of rejection have been traversed, accommodated, or rendered moot. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is encouraged to contact the undersigned at 202.942.5085 should any additional information be necessary for allowance.

Respectfully submitted,



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